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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

SURGICAL INSTRUMENT SERVICE COMPANY, INC.,
Plaintiff,
v.
INTUITIVE SURGICAL, INC.,
Defendant.

Case No. 3:21-cv-03496-AMO

DECLARATION OF KENNETH A. GALLO IN SUPPORT OF DEFENDANT'S MOTION FOR RECONSIDERATION OR, IN THE ALTERNATIVE, FOR CERTIFICATION OF AN INTERLOCUTORY APPEAL

The Honorable Araceli Martínez-Olguín

I, KENNETH A. GALLO, declare as follows:

1. I am an attorney licensed to practice in New York and the District of Columbia, and am admitted *pro hac vice* to practice before this Court. I am a partner with the law firm of Paul, Weiss, Rifkind, Wharton & Garrison LLP ("Paul, Weiss"), counsel for Intuitive Surgical, Inc. ("Intuitive") in this matter. I have personal knowledge of the facts set forth herein, and if called to testify, I could and would testify competently hereto.

2. I submit this declaration in support of Defendant's Motion for Reconsideration or, in the Alternative, for Certification of an Interlocutory Appeal, to identify the key FDA-related and post-2022 evidence that Intuitive would seek to introduce at trial if not excluded by the Court's rulings, and to describe the relevance of that evidence. Excluding the evidence described herein would cause severe prejudice to Intuitive.

3. Below, I provide a non-exclusive description of exhibits and testimony that Intuitive would expect to offer at trial should the Court grant its Motion for Reconsideration.[1]

A. SIS's Case Relies on Letters in Which Intuitive Expressed Its Concerns About EndoWrists Modified by Unauthorized Third Parties that Lacked FDA Clearance.

4. SIS has made clear that it intends to rely on certain letters that Intuitive sent to customers expressing Intuitive's concerns about the risks that unauthorized modified EndoWrists posted to patient safety as evidence of Intuitive's alleged anticompetitive conduct. SIS references these letters to hospitals in its complaint, and has made clear that it intends to argue that such letters were the cause of customers declining to do business with SIS. *See, e.g.*, Dkt. 1 ¶ 92 ("Between late 2019 to early 2020, Intuitive sent letters to and had in-person conversations with SIS's customers or potential customers, knowing that they were under contract or in contractual negotiations for repaired EndoWrists. As a result of the threats and misleading statements in those letters and conversations, all of SIS's EndoWrists customers backed out of their contracts or did not sign contracts under negotiation, effectively eviscerating SIS's EndoWrist repair business.").

[1] Intuitive reserves the right to offer other testimony (either through depositions or from live witnesses) or exhibits included on the Trial Exhibit List that are not explicitly discussed in this declaration.

Intuitive sent similar letters to third parties who were marketing unauthorized EndoWrists, and to the FDA. Significant to Intuitive's concerns in all of these letters was the fact that these unauthorized third parties had not proven—to the FDA or to Intuitive—that their products and services were equivalent in terms of safety, efficacy, performance, and reliability to Intuitive's original EndoWrists. This evidence is relevant to demonstrating that Intuitive's contractual policies regarding the use of unauthorized products and services with its system were reasonable and not anticompetitive, and also that it was reasonable and not anticompetitive for Intuitive to apply those policies with regard to the unauthorized instruments offered by Rebotix and SIS. In addition, this evidence is relevant to demonstrating that Intuitive's contracts do not require the exclusive use of Intuitive products and services, but rather permit the use of authorized or approved third-party products and services, and that this authorization or approval term is not illusory. Specifically, the evidence shows that Intuitive was willing to consider authorization of third parties that provided proof of FDA clearance or other clinical proof demonstrating that their modified EndoWrists were equivalent in specifications to original EndoWrists. I describe below examples of such evidence.

5. Attached hereto as Exhibit 1 is a true and correct copy of a document identified on the Trial Exhibit List as TX0556 (Intuitive-00373885 - Intuitive-00373887), a letter from Intuitive Surgical to Marin General Hospital dated November 26, 2019. The letter states that Intuitive discourages the use of unauthorized products and services that modify Intuitive products so they can be used to perform surgeries beyond the pre-programmed number of uses, explaining that each product is "evaluated by the [FDA] and/or other international regulatory agencies to assess the safety and effectiveness of [the] device over its intended life," that the FDA's 510(k) process helps "to protect the public health by ensuring that medical devices are shown to be either safe and effective or substantially equivalent to other devices," that "Intuitive products are designed and tested to achieve a targeted level of safety, precision, and dexterity over the programmed number of instrument uses," and that a "reduc[tion of] these levels of safety, precision and dexterity" may result from "continued use beyond the instrument's determined useful life." Ex. 1 (TX0556), at

-885 through -886. This letter is a representative example of letters that Intuitive sent to several customers regarding the use of unauthorized modified EndoWrists and that both parties have included on the Trial Exhibit List.

6. Attached hereto as Exhibit 2 is a true and correct copy of a document identified on the Trial Exhibit List as TX1441 and TX1635.018 (REBOTIX145274 - REBOTIX145279), an April 16, 2019, cease and desist letter from Intuitive to Rebotix, sent shortly before SIS began distributing Rebotix's modified EndoWrists. The letter details concerns about Rebotix's unauthorized marketing of modified EndoWrists, and explains the basis of those concerns. The letter demands that Rebotix stop modifying EndoWrists unless Rebotix could show that it or its "service centers" (which include third parties such as SIS) *either* "[a] received FDA clearance for the modifications to the EndoWrist instruments described herein *or* [b] possess clinical proof that your service process returns the modified instruments to a 'production equivalent qualification' and/or that additional use does not affect the safety or performance of the instruments." Ex. 2 (TX1441), at -279 (emphasis added). Attached hereto as Exhibits 3 through 8 are true and correct copies of documents identified on the Trial Exhibit List as TX1635.002 (REBOTIX140044 - REBOTIX140053), TX1635.003 (REBOTIX140654 - REBOTIX140662), TX1635.008 (REBOTIX144751 - REBOTIX144756), TX1635.009 (Restore-00086086 - Restore-00086092), TX1635.012 (Intuitive-00478439 - Intuitive-00478444), and TX1635.014 (Restore-00025577 - Restore-00025584) respectively, which are similar letters that Intuitive sent to other unauthorized third parties.

7. Attached hereto as Exhibit 9 is a true and correct copy of a document identified on the Trial Exhibit List as TX0259 (Intuitive-00552744 - Intuitive-00552759), a January 30, 2020, Intuitive email attaching a letter that it sent to the FDA on January 29, 2020. The email expresses Intuitive's concerns about "risk to patients" arising from EndoWrists that third parties have modified to work beyond the number of uses for which those instruments have been validated by Intuitive and previously cleared by the FDA. Ex. 9 (TX0259), at -745.

B. Intuitive's EndoWrists Were Cleared by the FDA as Limited Use Instruments.

8. Intuitive's concerns about the use of unauthorized and non-FDA-cleared instruments with its system were informed by its own history of FDA clearance. If not excluded, Intuitive would seek to present evidence to the jury in the form of documents and witness testimony showing that Intuitive was required to obtain, and did obtain, clearance from the FDA before it could begin marketing its da Vinci surgical system and EndoWrist instruments to customers in the United States; that the process of obtaining FDA clearance was long and costly, and involved submitting thousands of pages of reports detailing Intuitive's testing of its products; that the FDA initially cleared EndoWrists as limited-use instruments; and that the FDA required Intuitive to obtain a new Section 510(k) clearance when Intuitive sought to extend the use limit for certain newer-generation EndoWrist instruments. This evidence, key examples of which are detailed below, is relevant in that it tends to prove several facts that are disputed by the parties. For example, this evidence tends to show that the EndoWrist use limit is not "arbitrary," contrary to what SIS told its customers, Ex. 43, TX1551 (SIS094574 - SIS094595), at -584, but rather was the product of extensive testing and was cleared following regulatory review. This evidence also tends to show that Intuitive acted reasonably, and did not engage in anticompetitive conduct, when it told its customers that Intuitive's contracts did not permit the use of unauthorized modified EndoWrists that had not been cleared by the FDA and had not been proven to be equivalent in their specifications to Intuitive's original FDA-cleared EndoWrists.

9. Attached as Exhibits 10 through 17 are true and correct copies of documents identified on the Trial Exhibit List as TX1637.001 (Intuitive-00692611 - Intuitive-00692642), TX1637.002 (Intuitive-00692643 - Intuitive-00692821), TX1637.003 (Intuitive-00692822 - Intuitive-00692911), TX1637.004 (Intuitive-00692912 - Intuitive-00693153), TX1637.005 (Intuitive-00693154 - Intuitive-00693534), TX1637.006 (Intuitive-00693535 - Intuitive-00694042), TX1637.007 (Intuitive-00694043 - Intuitive-00694521), and TX1637.008 (Intuitive-00694522 - Intuitive-00694606). These exhibits are Volumes 1 through 8 of Intuitive's November 26, 1999, Premarket Application, titled "System 510k's/K990144 Premarket Application," seeking FDA clearance for additional instruments to be used with Intuitive's Endoscopic

Instrument Control System, including scissors, scalpels, forceps, clip applier, electrocautery and accessories, pick-ups and needle drivers/holder. These Exhibits document the information Intuitive provided to the FDA before it was allowed to begin marketing these EndoWrist instruments to customers in the United States. For example, these Exhibits show that Intuitive told the FDA that EndoWrist instruments were "re-usable (for a limited number of uses)" and "programmed for a limited number of uses to ensure reliability and consistent performance[.]" Ex. 11 (TX1637.002), at -662. These Exhibits also show that Intuitive submitted extensive testing data to the FDA validating the use limit on EndoWrist instruments. Ex. 16 (TX1637.007), at -251 through -301. In addition, these Exhibits show that certain EndoWrist instruments initially failed use-limit testing and had to be improved and re-tested/re-validated. Ex. 16 (TX1637.007), at -251 through -254, -260 through -272.

10. Attached hereto as Exhibit 18 is a true and correct copy of a document identified on the Trial Exhibit List as TX1377 (Intuitive-00691203 - Intuitive-00691207), which consists of a January 15, 1999, submission from Intuitive to the FDA titled "510(k) SUMMARY – Intuitive Surgical, Inc.[,]" and the FDA's July 11, 2000, clearance letter. Intuitive's submission describes its EndoWrists as "'Resposable' (limited reuse) Endoscopic Instruments." Ex. 18 (TX1377), at -204. The FDA's letter notes that it has determined Intuitive's EndoWrists are "substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices." Ex. 18 (TX1377), at -205. This Exhibit shows that, following review of Intuitive's submission, including the testing data described in Paragraph 9 above, the FDA granted Intuitive clearance to market EndoWrist instruments with a use limit.

11. Attached hereto as Exhibit 19 is a true and correct copy of a document identified on the Trial Exhibit List as TX0563 (Intuitive-00481167 - Intuitive-00481175), a January 4, 2002, letter from Intuitive to the FDA regarding "510(k) Premarket Notification (K013416) Intuitive Surgical® Endo Wrist™ Endoscopic Instruments Your Fax dated December 12, 2001." The Exhibit shows that the FDA asked Intuitive about how the use limit for the EndoWrist was determined and asked Intuitive to provide data to support the claim that the EndoWrist is

programmed with a use limit to "ensure reliability and consistent performance." Ex. 19 (TX0563), at -168. The Exhibit shows that Intuitive responded with data, *see* Ex. 19 (TX0563), at -170 through -172, including referring the FDA to data submitted in Ex. 16 (TX1637.007), as described above in Paragraph 9.

12. Attached hereto as Exhibit 20 is a true and correct copy of a document identified on the Trial Exhibit List as TX1408 (Intuitive-02054178 - Intuitive-02054182), a February 25, 2022, email between the FDA and Intuitive attaching the FDA's letter notifying Intuitive that the FDA has identified deficiencies with Intuitive's submission for 8mm EndoWrist instruments with extended lives. Among other deficiencies, FDA cited issues with the cleaning validation testing that Intuitive had submitted to support 510(k) clearance of its devices for extended use. *See* Ex. 20 (TX1408), at -180 ("You provided *Justification, Cleaning Efficacy for 18 Clinical Uses, da Vinci X/Xi 8mm Instruments* in Appendix B of your submission to justify relying on existing cleaning validation testing conducted with the predicate device (K170645) and not conducting new cleaning validation to support the extended uses of the da Vinci X/Xi 8 mm instruments. With your justification, you conducted testing on two device types used in reliability testing to demonstrate that two design features, distal seal and flush tube, maintain flow rate specifications over the extended simulated surgical use and reprocessing cycles. Although these features may mitigate ingress of soil and facilitate removal of soil, testing of these features is not adequate to demonstrate that the instruments can still be effectively cleaned following additional uses and reprocessing cycles."). Intuitive subsequently addressed these deficiencies in follow-up submissions to the FDA.

13. Attached hereto as Exhibit 21 is a true and correct copy of a document identified on the Trial Exhibit List as TX0729 (Intuitive-02067560 - Intuitive-02067568), an August 15, 2022, email between the FDA and Intuitive attaching the FDA's August 15, 2022, letter notifying Intuitive that the FDA has determined that Intuitive's 8mm EndoWrist instruments with extended lives have been determined to be substantially equivalent to Intuitive's predicate devices. This Exhibit shows that, after Intuitive submitted performance test data to the FDA, the FDA concluded

that these EndoWrist instruments with an increased number of lives were "substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices"—*i.e.*, EndoWrist instrument with a lower number of lives. Ex. 21 (TX0729), at -561, -566 through -568.

C. Rebotix Applied for FDA Clearance to Modify EndoWrists and Received a Deficiency Letter, After which Rebotix Withdrew Its Application.

14. In its marketing materials, SIS told customers that modified EndoWrists with reset use counters were equivalent to Intuitive EndoWrists, or had been restored to the equivalent of Intuitive's original specifications. But the FDA did not determine that Rebotix's modified EndoWrists, which SIS marketed to customers, were equivalent to original EndoWrists. As further detailed below, to the contrary, after Rebotix applied to the FDA for 510(k) clearance and a determination of equivalence, the FDA issued a deficiency letter in 2015 detailing 51 separate reasons why Rebotix had failed to satisfy the requirements for 510(k) clearance. Instead of addressing those deficiencies, Rebotix withdrew its application and continued to market its modified EndoWrists without FDA clearance. SIS thereafter became a distributor of Rebotix's modified EndoWrists, and made statements to customers about their equivalence with Intuitive's originals, which Intuitive will argue are false and misleading. I describe below examples of the evidence Intuitive would anticipate offering regarding Rebotix's application for 510(k) clearance and subsequent communications with the FDA. Evidence that Rebotix chose to seek FDA clearance is relevant to establishing the competitive significance of such clearance and tends to reflect that hospital customers prefer (if not require) the use of products and services cleared by the FDA. This evidence also tends to show that it was reasonable and not anticompetitive for Intuitive to adopt contractual limitations regarding the use of unauthorized products and services, including those offered by Rebotix and SIS, with its system. Further, this evidence tends to show that SIS's modified EndoWrists were not equivalent to Intuitive's original EndoWrists, and that SIS's contrary statements to customers were therefore false.

15. Attached hereto as Exhibit 22 is a true and correct copy of a document identified on the Trial Exhibit List as TX1424 (REBOTIX074144 - REBOTIX074148), a May 10, 2013, email with attached notes between AJW Technology Consultants, Inc. and Benjamin Biomedical,

the parent company of Rebotix. In the email, an AJW representative states that, "AJW . . . will support Benjamin Biomedical and a new entity in developing the following documentation: . . . Design History File [with the intent to have the data support a potential 510(k) submission]." Ex. 22 (TX1424), at -144 (brackets in original). The attached notes state, under the heading "REGULATORY CLASSIFICATION": "Serviced Wrists will be considered 'remanufactured' devices for FDA purposes because the serviced Wrists will have a useful life beyond that established by the OEM. As a result this project will require FDA registration, 510 (k) submission, and full compliance with 820 quality system requirements including Design controls." Ex. 22 (TX1424), at -146.

16. Attached hereto as Exhibit 23 is a true and correct copy of a document identified on the Trial Exhibit List as TX1437 (REBOTIX128997 - REBOTIX129042), a December 19, 2014, letter from the FDA "[a]cknowledg[ing]" receipt of Rebotix's submission titled "Traditional 510(k) Notification Re-manufactured EndoWrists." Ex. 22 (TX1437), at -997, -999. The FDA's letter states: "We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO." Ex. 23 (TX1437), at -997 (capitalization in original).

17. Attached hereto as Exhibit 24 is a true and correct copy of a document identified on the Trial Exhibit List as TX1425 (REBOTIX077545 - REBOTIX077548), an April 9, 2015, email from AJW Consultants to Benjamin Biomedical attaching an April 9, 2015, letter from the FDA. The FDA's letter states: "We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO." Ex. 24 (TX1425), at -547 (capitalization in original).

18. Attached hereto as Exhibit 25 is a true and correct copy of a document identified on the Trial Exhibit List as TX1428 (REBOTIX081742 - REBOTIX081746), which are Rebotix, LLC "Management Review Meeting" minutes dated May 4, 2015. These meeting minutes state:

"For financial and business considerations, Rebotix will not initiate production or ship remanufactured Endowrists until receiving marketing clearance from FDA. The 510 k application is currently under review." Ex. 25 (TX1428), at -742.

19. Attached hereto as Exhibit 26 is a true and correct copy of a document identified on the Trial Exhibit List as TX1453 (REBOTIX171030 - REBOTIX171058), a June 23, 2015, email from the FDA to Rebotix, attaching a letter of the same date, in which letter the FDA identifies 51 deficiencies in Rebotix's application for FDA clearance of modified EndoWrists. Among other things, the FDA specifically called out Rebotix's statement that "OEM-equivalent specifications have been derived from published OEM product information, in-house 'reverse engineering' activities, and the relevant requirements of applicable consensus standards." Ex. 26 (TX1453), at -053. The FDA noted that "it does not seem possible to identify exact device specifications using these methods," and called on Rebotix to "perform side-by-side comparative testing with the subject device and the matching OEM device model, and use a statistical comparison between the two devices to demonstrate substantial equivalence." Ex. 26 (TX1453), at -053. The FDA also directed Rebotix to "address the risk mitigation measures you have in place for addressing the issues in each recall" the FDA had previously issued with respect to EndoWrists, and "any methods by which recalled devices are identified and rejected as unacceptable candidates for remanufacture." Ex. 26 (TX1453), at -033.

20. Attached hereto as Exhibit 27 is a true and correct copy of a document identified on the Trial Exhibit List as TX0775 (REBOTIX077729 - REBOTIX077734), a July 9, 2015, email from the FDA to Rebotix, in which the FDA responds to questions from Rebotix about the FDA's deficiency letter and why the FDA required that Rebotix provide certain information.

21. Attached hereto as Exhibit 28 is a true and correct copy of a document identified on the Trial Exhibit List as TX0824 (REBOTIX146948 - REBOTIX146955), a June 25, 2020, email chain between Rebotix and the FDA where Rebotix responds to questions the FDA has raised, including: "Are you providing service that may extend the lives of devices beyond the original equipment manufacturer (OEM) stated limit. If yes, please provide information on how

many additional uses you extend the lives of the devices and how you confirm it remains safe and effective for its intended use (i.e. the performance and safety specifications are not significantly changed from the original performance and safety specifications)." Ex. 28 (TX0824), at -950.

22. Attached hereto as Exhibit 29 is a true and correct copy of a document identified on the Trial Exhibit List as TX0268 (REBOTIX175417 - REBOTIX175418), a November 16, 2021, letter from the FDA to Rebotix stating, among other things, that "the da Vinci S EndoWrist Instruments were cleared for a set number of uses. By extending the number of uses, your activities may be altering the intended use of the subject device. We have conducted a review of our files and are unable to identify an additional [FDA] clearance or approval supporting this intended use." Ex. 29 (TX0268), at -417.

23. Attached hereto as Exhibit 30 is a true and correct copy of a document identified on the Trial Exhibit List as TX0570 (REBOTIX175839 - REBOTIX175843), a July 22, 2022, email chain in which a representative of the FDA expresses concerns that "the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted." Ex. 30 (TX0570), at -840.

D. SIS Did Not Apply for FDA Clearance Itself and Its Witnesses Claim Not to Have Known the Outcome of Rebotix's Application for FDA Clearance.

24. SIS did not obtain FDA clearance for the modified EndoWrists that it marketed to customers; it relied on Rebotix's representation that FDA clearance was not required. SIS's Greg Posdal has testified that he was aware that Rebotix applied for FDA clearance but claims not to know the outcome of Rebotix's application. And SIS has admitted, in response to written discovery, that it did not attempt, after 2022, to obtain FDA clearance for modified EndoWrists or market any modified EndoWrist instruments (including FDA-cleared modified EndoWrists). This evidence is relevant to proving that the modified EndoWrists that SIS marketed to customers were not equivalent to Intuitive's EndoWrists, contrary to what SIS told its customers. This evidence also is relevant to proving that SIS chose not to compete by obtaining FDA clearance or marketing FDA-cleared modified EndoWrists, even after Intuitive announced on its website in 2023 that

customers were free to purchase any modified EndoWrist that had been cleared by the FDA, without consequence under Intuitive's contracts. This evidence also bears on the credibility of SIS's witnesses.

25. Attached hereto as Exhibit 31 is a true and correct copy of excerpts from the Rule 30(b)(1) deposition transcript of Greg Posdal of SIS, taken in this matter on November 1, 2022. Mr. Posdal testified that SIS never sought 510(k) clearance from the FDA for anything. Ex. 31 at 93:19–21. Mr. Posdal further testified that he "assume[d]" that he discussed the fact that Rebotix had applied for FDA clearance, but did not know the outcome of Rebotix's Section 510(k) clearance for its EndoWrist reset process, and did not know whether the FDA found deficiencies in Rebotix's FDA application. Ex. 31 at 54:23–55:19.

26. Attached hereto as Exhibit 32 is a true and correct copy of excerpts from the Rule 30(b)(6) deposition transcript of Greg Posdal of SIS, taken in this matter on November 1, 2022. Mr. Posdal testified that SIS did not take any independent steps to ensure that the modified EndoWrists that it marketed to customers complied with FDA requirements. Ex. 32 at 61:20–24. Mr. Posdal also testified that SIS "relied on Rebotix" for the conclusion that modifying EndoWrist instruments to reset the use counter does not require FDA clearance, and that SIS did not independently consider that question. Ex. 32 at 45:19–46:15.

27. Attached hereto as Exhibit 33 is a true and correct copy a document identified on the Trial Exhibit List as TX1701, SIS's Responses to Intuitive's Second Set of Requests for Admissions. SIS admitted that it "did not, after November 2022, whether alone or with a third party, seek FDA clearance for any service, procedure, or technology for resetting or reprogramming the use counter on any EndoWrist Instrument." Ex. 33 (TX1701) at 3–4. SIS further admitted that it "did not, after November 2022 . . . sell, distribute, or market any EndoWrist Instruments with reset and/or reprogrammed use counters, or any service for resetting or reprogramming the use counter on EndoWrist Instruments." Ex. 33 (TX1701) at 5.

E. Iconocare Obtained FDA Clearance to Market a Modified EndoWrist, and Intuitive Subsequently Announced that Customers Were Free to Purchase

FDA-Cleared Modified EndoWrists Without Consequence Under Intuitive's Contracts.

28. In 2019, around the same time that SIS became a distributor of Rebotix's non-FDA-cleared, unauthorized modified EndoWrists, another third party (Restore, through its affiliate Iconocare) began working on an application to the FDA for 510(k) clearance to modify EndoWrists. Iconocare received 510(k) clearance to modify a particular EndoWrist instrument in September 2022, after the FDA had reviewed its application and determined the modified EndoWrist to be substantially equivalent to Intuitive's original EndoWrist. Iconocare was the first entity to obtain FDA clearance to modify EndoWrists. Thereafter, Intuitive announced on its website that customers were free to purchase any modified EndoWrist that had been cleared by the FDA, without consequence under Intuitive's contracts. This evidence is relevant to show that Intuitive's authorization or approval process for third-party products and services is not illusory. As discussed above, Intuitive previously had asked third parties for proof that their modified EndoWrists were cleared by the FDA or had been clinically proven to be equivalent to Intuitive's original EndoWrists. *See supra* Paragraph 6. Iconocare chose to have its products cleared by the FDA and Intuitive authorized customers to purchase those products under its contracts. This evidence tends to show that Intuitive's contracts were not exclusive dealing or tying arrangements, and that Intuitive had reasonable, pro-competitive justifications for requiring approval for third-party modified EndoWrists. This evidence also shows that third parties were able to obtain approval to market modified EndoWrists, and that SIS's failure to do so was the result of a choice by SIS.

29. Attached hereto as Exhibit 34 is a true and correct copy of a document identified on the Trial Exhibit List as TX1300 (ACG000006 - ACG000007), an April 9, 2019, memorandum to Restore Robotics from Arkin Consulting Group titled "Discussions with FDA about EndoWrist counter." The document states: "The Endowrist is the issue because Restore Robotics wants to reset the counter which then changes the device original specifications. To get FDA to accept this, they will need to [l]earn what the DaVinci specs are for each device[:] a) Develop a robust protocol that would prove that the device can withstand uses greater than those specified by the

manufacturer. b) Implement said protocol." Ex. 34 (TX1300), at -007 (emphasis in original). Restore subsequently submitted an application for 510(k) clearance to the FDA through its affiliate, Iconocare.

30. Attached hereto as Exhibit 35 is a true and correct copy of a document identified on the Trial Exhibit List as TX1305 (AHP002623 - AHP002624), a February 13, 2021, letter from Iconocare to the FDA [redacted].

31. Attached hereto as Exhibit 36 is a true and correct copy of a document identified on the Trial Exhibit List as TX0334 (AHP000526 - AHP000537), a March 30, 2021, email from the FDA to Iconocare, [redacted].

32. Attached hereto as Exhibit 37 is a true and correct copy of a document identified on the Trial Exhibit List as TX0216 (Restore-00099136 - Restore-00099139), an October 1, 2022, email from Alliance Healthcare Partners to Restore, attaching a September 30, 2022, letter from the FDA. The letter shows that the FDA reviewed Iconocare's Section 510(k) premarket notification of intent to market remanufactured 8mm Monopolar Curved Scissors, and that the FDA determined the remanufactured device is substantially equivalent to Intuitive's legally

marketed predicate devices. The FDA therefore cleared Iconocare to "market the device." Ex. 37 (TX0216), at -137.

33. Attached hereto as Exhibit 38 is a true and correct copy of a document identified on the Trial Exhibit List as TX1660, titled "Da Vinci Surgical Instruments | Intuitive." This is Intuitive's March 2023 statement on its website concerning usage limits and remanufactured EndoWrist instruments. Among other statements, Intuitive states that "Intuitive will not void its service contract with, cease doing business with, or consider it a breach of contract by a customer . . . who chooses to purchase remanufactured instruments that have been remanufactured by a third party pursuant to and in compliance with a 510(k) clearance or equivalent granted by the FDA." Ex. 38 (TX1660) at 3.

F. Hospitals Care About FDA Clearance.

34. At the pretrial conference, the Court noted "hesitation" in granting SIS's motions relating "to Intuitive's ability to argue that customers cared about the [FDA] clearance and, thus, SIS' failure to obtain it impacts antitrust causation and damages." November 25, 2024, Hr'g Tr. at 36:8–11. To try to prove antitrust causation and damages at trial, SIS has repeatedly made clear that it will argue that hospitals' demand for its EndoWrist modification services was "monumental." Evidence that hospitals and surgeons cared about whether the surgical instruments they used on patients were FDA-cleared tends to rebut SIS's arguments about the level of demand for modified EndoWrists that had not been cleared by the FDA. Similarly, evidence that hospitals that actually bought or sampled modified EndoWrists from Restore and Rebotix because they mistakenly believed that such products *had* been cleared by the FDA also tends to undercut SIS's arguments about customer demand. I describe below examples of such evidence.

35. Attached hereto as Exhibit 39 is a true and correct copy of excerpts from pages 151–154 of the deposition transcript of Edward Harrich. Mr. Harrich testified that Pullman Regional Hospital received information, before it started using Rebotix's services, that Rebotix had received "the 510(k) approval"—meaning, in Mr. Harrich's understanding, that "they're approved to reprogram the EndoWrist." Ex. 39 at 151:2–16. Mr. Harrich further explained that

"[h]aving FDA backing to reprocess or reprogram those chips" in the EndoWrists was "an important factor" for Pullman, because "we like to stay with FDA approval on everything we're using and doing." Ex. 39 at 154:5–11.

36. Attached hereto as Exhibit 40 is a true and correct copy of excerpts from pages 76–78 of the deposition transcript of Tyler McDonald. In this testimony, Mr. McDonald explained that Conway Regional Health System did not know that Restore did not have 510(k) clearance prior to purchasing Restore's services to remanufacture EndoWrist instruments, but that he would have wanted to know that fact because 510(k) clearance is a "general marker of reputability." Ex. 40 at 78:5–6.

37. Attached hereto as Exhibit 41 is a true and correct copy of excerpts from page 132 of the deposition transcript of Stacey Donovan. Ms. Donovan testified that she did not think that her hospital, EvergreenHealth, "would do business with an organization that I'm aware of that doesn't have a[n] FDA clearance, at least not knowingly." Ex. 41 at 132:9–11.

38. Attached hereto as Exhibit 42 is a true and correct copy of excerpts from pages 54–55, 57–59, and 82 of the deposition transcript of Ricardo Estape. Dr. Estape, who serves as director of the Hospital Corporation of America's Florida Institute for Gynecologic Oncology, stated his understanding that EndoWrists have a limited number of uses because when Intuitive "went for the FDA clearance, they went for whatever number that they thought they could maintain it working functionally well," and that "those were the numbers that they used, based on what FDA cleared them to use." Ex. 42 at 55:2–11. Dr. Estape further recalled that when a representative of Revanix Biomedical, another unauthorized third party, told him they could "wipe out the number of uses on an instrument that's FDA cleared for only ten uses," Ex. 42 at 57:20–21, he found that to be very "shady," because "it didn't seem like a very up-and-up program. . . . It surely didn't sound like the right thing to do," Ex. 42 at 58:2–13. Dr. Estape testified specifically that he is "not willing to do something that's not FDA approved because . . . anything that happens to the patient, they're going to come down on me for having used equipment that was not FDA approved at that time." Ex. 42 at 59:18–22. He added that he would not "be amenable to using a third party to

reset the counters on an EndoWrist if it did not have 510(k) clearance from the FDA." Ex. 42 at 82:2–5.

39. Attached hereto as Exhibit 43 is a true and correct copy of a document identified on the Trial Exhibit List as TX1551 (SIS094574 - SIS094595), titled "Surgical Instrument Service Co., Inc. da Vinci® EndoWrist® Repair FAQs." This document includes as the very first "frequently asked" question by hospital customers: "Can you send me your certification / FDA approval?" Ex. 43 (TX1551), at -578.

40. Attached hereto as Exhibit 44 is a true and correct copy of a document identified on the Trial Exhibit List as TX1464 (Restore-00010153 - Restore-00010156), a July 12, 2019, email chain between Rick Ferreira of Iconocare and other individuals affiliated with Restore Robotics titled "FW: Restore Robotics Follow Up." Ferreira comments on a piece of marketing material that SIS had sent to a customer and suggests: "Let's draft a list of questions for this potential customer to ask SIS. . . . Ask is the facility where these are repaired ISO certified and FDA Registered . . . . Ask why there is not a 510(k) requirement for this repair since it is a 'limited-use' reusable." Ex. 44 (TX1464), at -153. This document tends to show that Restore understood that hospital customers would want to know about SIS's and Rebotix's 510(k) clearance status before deciding whether to purchase their EndoWrist modification services.

41. Attached hereto as Exhibit 45 is a true and correct copy of a document identified on the Trial Exhibit List as TX1472 (Restore-00061148 - Restore-00061149), a June 27, 2018 email between Restore and Maximum Surgical Solutions, in which a representative of Maximum Surgical Solutions writes to Restore: "I was asked specifically today if this was an FDA approved program by Univ of Cincinnati. Univ of Cincinnati has two Si's in-house . . . . I explained that this was a restore/repair program, and he said for our program to meet their risk management approval, that he would need the certification or documentation to denote the process additional to the ISO documentation we provide[.] I know you cautioned not to infer that this process was anything FDA oriented so what could I provide him to try and take next steps? Do you have documentation

on the true differences between reprocessing and restoration that could increase our credibility on the process?" Ex. 45 (TX1472), at -148.

42. Attached hereto as Exhibit 46 is a true and correct copy of excerpts from pages 29–32, 55–56, and 92–95 of the June 7, 2021 deposition of Rick Ferreira. Mr. Ferreira, who worked with Restore Robotics to submit a 510(k) application on behalf of Iconocare, testified that the "real advantage" of 510(k) clearance was "the marketing piece of it," Ex. 46 at 30:23–24, because "when the FDA gives you a 510(k) clearance, it's telling the marketplace that they've looked at the predicate device, the new device, and that your methodologies for cleaning, function testing the device, and sterilizing it is equal to the predicate device," Ex. 46 at 31:11–16. Mr. Ferreira further testified that even though his opinion was that 510(k) clearance was not required in this instance, "from a marketing standpoint to be able to say to the customer this device basically has a Good Housekeeping seal of approval from FDA, that's why we pursued the 510(k)." Ex. 46 at 95:4–7.

43. Attached hereto as Exhibit 47 is a true and correct copy of excerpts from pages 96, 100, 223, and 228–229 of the deposition of Glenn Papit, of Rebotix. Mr. Papit testified about hospitals wanting to know if Rebotix's EndoWrist remanufacturing service was FDA-approved, and "getting shut down" by hospitals who insisted that Rebotix needed 510(k) clearance. Ex. 47 at 228:23.

44. Attached hereto as Exhibit 48 is a true and correct copy of excerpts from pages 52–53, 149–153, and 157 of the deposition of David Fabricant of Stryker. Mr. Fabricant testified about the fact that Stryker, which runs a major medical device reprocessing business, had considered acquiring Rebotix's assets for modifying EndoWrist instruments. Mr. Fabricant testified that Stryker would not have offered EndoWrist modification services to hospital customers without first obtaining FDA 510(k) clearance. Mr. Fabricant further testified that Rebotix's representatives informed Stryker that the FDA had "issued a deficiency letter," Ex. 48 at 149:24, and that Rebotix wanted to "leverage . . . Stryker's R&D for testing and regulatory for FDA engagement," Ex. 48 at 150:14–15. Mr. Fabricant testified that Rebotix was "roughly 30

percent to Stryker's standard for being able to go back to the FDA with a response." Ex. 48 at 150:12–13.

45. Attached hereto as Exhibit 49 is a true and correct copy of a document identified on the Trial Exhibit List as TX1439 (REBOTIX139042 - REBOTIX139045), a December 10, 2015, letter from Stryker to Rebotix. In its letter to Rebotix, Stryker expressed interest in acquiring Rebotix but included language concerning the importance of 510(k) clearance: "Key determinants of value include, but are not limited to: . . . (ii) the ability of the Company to transfer to Stryker its . . . design history file . . . and records of correspondence with the FDA; . . . (iv) the ability of the Company to transfer to Stryker responsibility for all activities related to 510(k) clearance and product commercialization . . . . We propose to acquire the Product Line for a total potential consideration of US $13.5 million, payable as follows: . . . a milestone payment of $0.5 million, payable upon 510(k) clearance . . . . Our ongoing due diligence review would include . . . FDA and regulatory due diligence." Ex. 49 (TX1439), at -042 through -043.

46. Attached hereto as Exhibit 50 is a true and correct copy of the December 2, 2022, report of SIS damages expert Richard F. Bero. On page 4 of his report, in a section titled "Basic damages assumptions," Mr. Bero describes two alternative damages scenarios he analyzed regarding SIS's antitrust claims, and explained that in both of them, he assumed that "SIS would not need FDA approval to make its repairs." Ex. 50 at 5. At trial, Intuitive will cross examine Mr. Bero about this assumption, his failure to account for the impact of SIS's lack of FDA clearance on hospital demand, and his failure to account for the competition that SIS might face from third parties with FDA clearance in a "but-for" world.

G. SIS's Experts Admit that FDA 510(k) Clearance Is Relevant to Issues of Safety and Efficacy in the Context of This Case.

47. SIS's own experts have admitted how evidence relating to the FDA's 510(k) clearance process is relevant to issues of safety and efficacy in the context of this case. Specifically, SIS's experts have explained how a 510(k) determination indicates whether a medical device product has been proven to be "as safe and effective" as its predicate device, and have opined that the FDA's clearance of Iconocare's modified EndoWrist demonstrates that particular

product to be as safe and effective as Intuitive's original EndoWrists. This evidence is relevant to showing why Intuitive's policies concerning unauthorized third-party products and services are reasonable and not anticompetitive. Specifically, such admissions tend to show that it was reasonable for Intuitive to adopt a policy of not approving or authorizing the use with its systems of third-party modified devices that had not been proven—either to the FDA or to Intuitive—to be at least equivalent in safety and efficacy to Intuitive's original devices. Likewise, this evidence tends to show why it was reasonable for Intuitive to distinguish for purposes of contractual authorization between such unproven devices and ones, like Iconocare's, that had received FDA clearance determining them to be equivalent in safety and efficacy to Intuitive's original EndoWrists.

48. Attached hereto as Exhibit 51 is a true and correct copy of the expert report of Philip J. Phillips, SIS's FDA expert, dated December 2, 2022. The report states, at ¶ 20, that "[t]he objective of FDA device regulation is to provide the American public with reasonable assurance of the safety and effectiveness for all medical devices,", and, at ¶ 24, that "FDA regulation of devices provides a 'reasonable assurance of safety and effectiveness.'" The report further states, at ¶ 29: "The purpose of a 510(k) submission is to demonstrate that a medical device is substantially equivalent ('SE') to a predicate device, which is basically a legally marketed class I or class II device. A medical device is determined to be SE to a predicate device if: (1) it has the same intended use as the predicate device; and (2) it has the same technological characteristics as the predicate device; or (3) it has different technological characteristics which do not raise new questions of safety and effectiveness and is shown to be 'as safe and effective' as the predicate device." At ¶ 121, the report explains that "Iconocare Health provided performance data to FDA that demonstrated that '. . . the reprocessed devices are as safe and effective as the predicate and operate as originally intended.' Furthermore, the company convinced FDA that testing each individual device before release establishes the '. . . appropriate function of its components prior to packaging and labeling operations.'" Mr. Phillips goes on, in the same paragraph, to opine: "It

is not surprising that FDA determined the device to be SE as it is virtually identical to the predicate devices in all respects and one would anticipate that they are as safe and effective."

49. Attached hereto as Exhibit 52 is a true and correct copy of the December 2, 2022, report of SIS economic expert Dr. Russell Lamb. In ¶¶ 129–132 of his report, Dr. Lamb adopts and relies upon Mr. Phillips' opinions regarding Iconocare's 510(k) clearance, and cites this as evidence that "despite Intuitive's claims to the contrary, EndoWrist instruments repaired or reprocessed by third parties such as SIS were equally as safe as the newly manufactured replacement EndoWrist instruments hospitals were required to purchase directly from Intuitive"—which he argues undercuts Intuitive's stated pro-competitive justification for its contracts. Dr. Lamb also references FDA clearance as the basis for other opinions in his report. For example, at ¶¶ 46–48, Dr. Lamb opines that non-minimally invasive soft tissue ("MIST") surgical robots are not economic substitutes for MIST surgical robots, like the da Vinci, and in reaching this conclusion notes that no other surgical robots have FDA clearance to perform all of the same procedures as the da Vinci. Likewise, at ¶ 64 of his report, Dr. Lamb opines that EndoWrist repair and replacement is a relevant product market, relying on the fact that "no other manufacturers sell FDA-approved surgical instruments for use with a da Vinci."

H. FDA-Related Evidence Is Relevant to Showing that Intuitive's Design Changes to X/Xi EndoWrists Were Genuine Product Improvements and Not Anticompetitive.

50. SIS claims that Intuitive's incorporation of a wireless RFID chip with enhanced encryption technology in its X/Xi EndoWrists was anticompetitive, and not a genuine product improvement. As part of rebutting that claim, Intuitive would expect to point to evidence that the FDA specifically required Intuitive to provide information addressing safety and efficacy concerns involving the wireless technology, including but not limited to concerns related to data security. In connection with seeking FDA clearance for its Xi da Vinci systems, which included the wireless RFID chip, Intuitive submitted to FDA a risk assessment that identified potential cybersecurity risks associated with the product, including risks related to the RFID chip, and mitigation measures that Intuitive had put in place to address those risks. Among the "critical" cybersecurity risks

identified by Intuitive was the potential for interference with data on the RFID chip (which includes data related to use limits). Intuitive reported to FDA in 2013 that the mitigation measures it undertook to address this "critical" risk included encrypting the data on the RFID chip itself as well as the wireless communications between the chip and the da Vinci. This evidence tends to show that Intuitive enhanced the encryption technology on X/Xi EndoWrists for legitimate reasons, relating to safety and efficacy and to preventing data breaches.

51. Attached hereto as Exhibit 53 is a true and correct copy of a document identified on the Trial Exhibit List as TX0566 (Intuitive-00506505 – Intuitive-00506641), Intuitive's FDA submission including the "Cybersecurity Risk Analysis" submitted to FDA. The document specifically identifies "critical" risks associated with the "RFID reader" on the da Vinci and the "RFID tag" on the EndoWrist instruments including that "[c]ompromise of the interface leads to modification of instrument" resulting in it being "[p]ossible to use surgical instruments beyond tested life." Ex. 53 (TX0566), at -542. Intuitive further reported to FDA the mitigation measures it undertook to address these "critical" risks including that the wireless communications are "encrypted" as is data on the RFID chip itself. Ex. 53 (TX0566), at -542.

52. Attached hereto as Exhibit 54 is a true and correct copy of a document identified on the Trial Exhibit List as TX1351 (Intuitive-00499468 - Intuitive-00499756), Intuitive's February 19, 2014, response to FDA comments specifically requiring Intuitive to provide additional information to "address the safety and effectiveness concerns involving the wireless technology" including but not limited to concerns related to "data security." Ex. 54 (TX1351), at -640. Intuitive's response addresses each of FDA's safety and effectiveness concerns with wireless technology including those related to "data security" and provides information both on how data security would be addressed on the RFID chip itself as well as in connection with the wireless transmission of that data. Ex. 54 (TX1351), at -640 through -642.

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: December 16, 2024

By: /s/ *Kenneth. A. Gallo*
Kenneth A. Gallo